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09/737,004	12/14/2000	Suzanne F. Groemminger	P02977	8548

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EXAMINER

DELCOTTO, GREGORY R

ART UNIT	PAPER NUMBER
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1751

DATE MAILED: 04/22/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/737,004

Applicant(s)

GROEMMINGER, SUZANNE F.

Examiner

Gregory R. Del Cotto

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 13-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Claims 1-20 are pending. Applicant's arguments and amendments filed 2/7/03 have been entered. Claims 13-20 are withdrawn from consideration as being drawn to a non-elected invention.

Applicant's election of Group I, claims 1-12 in Paper No. 5 and 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

### **Objections/Rejections Withdrawn**

2. The following objections/rejections as set forth in Paper #5 have been withdrawn:

The rejection of claims 1-12 under 35 USC 112, second paragraph, has been withdrawn.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/37049.

'049 teaches an ophthalmic solution for the treatment of contact lenses while worn in the eye containing an ethoxylated glucose derivative, tyloxapol, and a polyoxyethylene-polyoxypropylene nonionic surfactant. See Abstract. The ethoxylated glucose derivative functions as the wetting agent. See page 5, lines 20-30. The nonionic polyoxyethylene-polyoxypropylene surfactants have an HLB of at least 18. such surfactants can be selected from the group of commercially available surfactants having the name poloxamine or poloxamer. Poloxamine surfactants consist of a poly(oxypropylene)-poly(oxyethylene)adduct of ethylene diamine having a molecular weight from about 7,500 to about 27,000 wherein at least 40 weight percent of said adduct is poly(oxyethylene). These are sold under the tradename Tetronic. An analogous series of surfactants is the poloxamer series which is a polyoxyethylene, polyoxypropylene block polymer under the trademark Pluronic. See page 6, lines 1-20.

Optionally, additional compatible surfactants that are known to be useful in contact lens wetting or rewetting solutions can be used in the solutions. Suitable nonionic surfactants include polyethylene glycol esters of fatty acids such as polysorbate 20, polyoxyethylene (23) lauryl ether, etc. See page 7, lines 10-20.

Additionally the composition may include nonionic polymeric demulcent and viscosity

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builder. Suitable viscosity builders include hydroxyethyl methylcellulose, etc. See page 7, lines 30-45. The compositions will also contain a disinfecting amount of a preservative or antimicrobial agent such as the hydrochloride salt of polyhexamethylene biguanide, etc. See page 8, lines 15-40. The pH of the composition should be maintained within the range of 5.0 to 8.0 and suitable buffers include boric acid, sodium borate, etc. See page 9, lines 20-30.

'049 does not specifically teach a cleaning solution containing a non-amine polyethyleneoxy-containing material, a first nonionic surfactant, a second nonionic surfactant, a wetting agent, and the other requisite components of the composition in the specific proportions as recited by the instant claims.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to formulate a cleaning solution containing a non-amine polyethyleneoxy-containing material, a first nonionic surfactant, a second nonionic surfactant, a wetting agent, and the other requisite components of the composition in the specific proportions as recited by the instant claims, with a reasonable expectation of success and similar results with respect to other disclosed components, because the broad teachings of '049 suggest a cleaning solution containing a non-amine polyethyleneoxy-containing material, a first nonionic surfactant, a second nonionic surfactant, a wetting agent, and the other requisite components of the composition in the specific proportions as recited by the instant claims.

Claims 1-4 and 6-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/43373.

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'373 teaches compositions and methods used in the eye and/or out of the eye inhibitors of proteinaceous deposits on hydrophilic contact lenses. See Abstract. A disinfecting amount of antimicrobial agent may be used such as hexamethylene biguanides and their polymers and water-soluble salts. See page 9, lines 10-25. Neutral or nonionic surfactants may impart cleaning and conditioning properties and are usually present in amounts up to 15 weight percent. The surfactants usually have a hydrophilic-lipophile balance (HLB) of 12.4 to 18.8. Satisfactory nonionic surfactants include polyethylene glycol esters of fatty acids such as polysorbate 20, polyoxyethylene (23) lauryl ether, etc. Other nonionic surfactants include poly(oxypropylene)-poly(oxyethylene) adduct of ethylene diamine having a molecular weight from about 7,500 to about 27,000. It may also be desirable to include water-soluble viscosity builders such as hydroxyethyl or hydroxypropyl cellulose, etc. Additionally, active ingredients such as tonicity agents, buffers, and sequestering agents may be added. In order to maintain the pH of the cleaning and conditioning solutions within the range of 3 to 9, suitable buffers may be added such as boric acid, sodium borate, etc. See page 11, lines 20-35.

'373 does not specifically teach a cleaning solution containing a non-amine polyethyleneoxy-containing material, a first nonionic surfactant, a second nonionic surfactant, a wetting agent, and the other requisite components of the composition in the specific proportions as recited by the instant claims.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to formulate a cleaning solution containing a non-amine

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polyethyleneoxy-containing material, a first nonionic surfactant, a second nonionic surfactant, a wetting agent, and the other requisite components of the composition in the specific proportions as recited by the instant claims, with a reasonable expectation of success and similar results with respect to other disclosed components, because the broad teachings of '373 suggest a cleaning solution containing a non-amine polyethyleneoxy-containing material, a first nonionic surfactant, a second nonionic surfactant, a wetting agent, and the other requisite components of the composition in the specific proportions as recited by the instant claims.

### ***Response to Arguments***

With respect to '049, Applicant states that '049 teaches away from the compositions of the present invention because '049 teaches that ethoxylated glucose derivative, which are identified in the instant specification as suitable high-HLB PEO-containing components) serve also as the wetting agent, thus teaching away from the compositions of the present invention. In response, note that, the Examiner maintains that the term "wetting agent" as recited by the instant claims would encompass ethoxylated glucose derivatives as taught by '049; in fact '049 teaches that ethoxylated glucose functions as a wetting agent in a similar contact lens treatment solution (See page 5, lines 20-30 of '049). Thus, the ethoxylated glucose derivatives as taught by '049 would fall within the broad class of "wetting agents" as recited by instant claim 1.

Additionally, '049 teaches the inclusion of other nonionic surfactant materials such as surfactants under the tradename of Pluronic which would fall within the scope of PEO containing materials having an HLB value of at least 18.

With respect to '373, Applicant states that '373 teaches away from the compositions of the present invention because '373 teach and/or suggest that moderately charged polyquaternium polymers are necessary in a composition to achieve an effective contact lens cleaning solution. Note that, the Examiner asserts that the instant claims recite "comprising" which would not exclude the presence of moderately charged polyquaternium polymers as taught by '373.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory R. Del Cotto whose telephone number is (703) 308-2519. The examiner can normally be reached on Mon. thru Fri. from 8:30 AM to 6:00 PM.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yogendra Gupta can be reached on (703) 308-4708. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3599 for regular communications and (703) 305-3599 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

GREGORY DELCOTTO  
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Gregory Delcotto', written over the printed name and title.

GRD  
April 19, 2003